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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,617	09/20/2005	Thomas Gostelow	0119/0047	8144

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EXAMINER

LOPEZ, AMADEUS SEBASTIAN

ART UNIT PAPER NUMBER

3771

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/549,617

Applicant(s)

GOSTELOW, THOMAS

Examiner

Amadeus S. Lopez

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

The examiner acknowledges the amendments made to the specification and hereby removes the objections as set forth in the office action filed on 6/14/2006.

### ***Response to Arguments***

Applicant's arguments, see page 5, filed 9/12/2006, with respect to claim 3 have been fully considered and are persuasive. The rejection of claim 3 has been withdrawn based on the currently amended claim.

Applicant's arguments, see page 5, filed 9/12/2006, with respect to claim 7 have been fully considered and are persuasive. The rejection under 35 U.S.C. 112, first paragraph of claim 7 has been withdrawn.

Applicant's arguments, see page 6, filed 9/12/2006, with respect to the rejection(s) of claim(s) 1-10 under 35 U.S.C. 102(b) and 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Arkinstall (5287852) in view of McCoy (6840242).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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**1. Claim 1 and 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Arkinstall (5287852).**

As to claim 1, what Arkinstall discloses in Fig. 1-3 is a tracheostomy device including a tubular member (12) adapted to provide a gas passage into the trachea (Fig. 2; formed by 62, 58) through an opening in neck tissues and an external retainer (14) for retaining the tubular member with the external surface of the neck adjacent the opening, characterized in that the patient end of the tubular member terminates adjacent the internal end of the opening, and that the device includes an internal retainer (68) for retaining the tubular member with the internal surface of the trachea adjacent the opening.

As to claim 9, Arkinstall discloses in figs. 1-3 a tracheostomy device characterized in that the external retainer (14; Fig. 2) is a flange and that the internal retainer (68) is a displaceable member (Col. 7, line 55 to Col. 8. line 2).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. **Claims 2-6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arkinstall (5287852) in view of McCoy (6840242).**

3. **With regards to claim 2**, what is taught and shown by Arkinstall in Figs. 1-3 is a tracheostomy device with all the limitations of the claim with the exception of wherein the device includes a seal for substantially sealing the trachea above the opening into the trachea. McCoy discloses in figs. 1-3 that the device includes a seal (21; Fig. 2 and 3) for substantially sealing the trachea above the opening into the trachea (Fig. 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tracheostomy device of Arkinstall to include a seal for substantially sealing the trachea above the opening into the trachea in order to collect secretions that accumulate so that it does not interfere with the tracheostomy device and opening as taught by McCoy (Col. 3, lines 1-21).

4. **With regards to claim 3**, what is taught and shown by McCoy in Figs. 1-3 is a tracheostomy with all the limitations of the claim with the exception of wherein the device is characterized in that the seal includes a fluid passage opening at one end of the seal and extending out of the trachea via the opening. McCoy discloses in Figs. 1-3 a tracheostomy device wherein the device is characterized in that the seal (21) includes a fluid passage opening (52) at one end of the seal (21) and extending out of the trachea via the opening. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Arkinstall to include a

seal including a fluid passage opening at one end of the seal and extending out of the trachea via the opening in order to suction any secretions, such as mucus, that accumulate in the seal (21) for removal from the body before the collection receptacle seal becomes saturated and begins to contaminate the tracheostomy device and cause infection.

5. **With regards to claim 4**, what is taught and shown by Arkinstall in Figs. 1-3 is a tracheostomy device with all the limitations of the claim with the exception of wherein the device is characterized in that the fluid passage is a suction passage. McCoy discloses in Figs. 1-3 is a tracheostomy device characterized in with a fluid passage (48 and 52) that acts as a suction passage (see abstract). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Arkinstall to include a seal including a fluid suction passage in order to suction any secretions, such as mucus, that accumulate in the seal (21) for removal from the body before the collection receptacle seal becomes saturated and begins to contaminate the tracheostomy device and cause infection.

6. **With regards to claims 5 and 6**, what is taught and shown by Arkinstall is a tracheostomy device with all the limitations of the claim with the exception of wherein the seal includes a deformable annular ring arranged to engage the surface of the trachea. McCoy discloses in Figs. 1-3, a tracheostomy device characterized in that the seal includes a deformable annular ring (21; In Col. 4, lines 8-60, McCoy states that the collection receptacle 21 is inflatable/deflatable and is therefore "deformable") arranged to engage the surface of the trachea (See Fig. 1 and 3 where it is shown that collection

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receptacle 21 is a ring and engages the wall of the trachea). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have a deformable and inflatable annular ring arranged to engage the surface of the trachea because the inflatable/deformable feature of the seal would allow the seal to accommodate different sized tracheas and allow for easy removal and insertion.

7. **With regards to claim 8**, what is not disclosed by Arkinstall but is taught and shown by McCoy in Figs. 1-3 is a tracheostomy device characterized in that the seal (21) includes a web (70) extending across the ring (See Fig. 3; Col. 5, lines 2-11; McCoy discloses that film 70 provides a soft and deformable cover for the collection receptacle which is designed so that the width or diameter of the collection receptacle 21 is such as to provide a seal within the trachea). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tracheostomy device of Arkinstall to include a seal that includes a web extending across the ring because it helps collect secretions that accumulate and further this web would allow the collection receptacle seal 21 to "substantially conform to the anatomical surface of the trachea."

8. **Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arkinstall in view of McCoy as applied to claim 5 above, and further in view of US Patent No. 5638813 to Augustine.**

9. **With regards to claim 7**, what is taught by Arkinstall in view of McCoy is a tracheostomy device with all the limitations of claim 7 with the exception of that the annular ring (21) includes a resilient foam. What is taught by Augustine is a tracheal

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tube with a self supporting tracheal tube cuff composed by one or more compressible, resilient parts between the tracheal tube and the cuff. "Such parts may be, for example, compressible, annular foam plastic or form rubber disks or washers surrounding the tube within the cuff..." "The compressed foam disk create a static low pressure seal between the cuff and the tracheal wall, throughout the respiratory cycle." Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tracheostomy device of Arkinstall/McCoy to make the annular ring include a resilient foam because it is well known in the art as taught by Augustine that annular rings made of foam provide good low pressure seals between the cuff and the tracheal wall, throughout the respiratory cycle so that it as comfortable for the user as possible without causing much irritation.

### ***Allowable Subject Matter***

Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### **Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amadeus S. Lopez whose telephone number is (571) 272-7937. The examiner can normally be reached on Mon-Fri 8:00AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO

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Customer Service Representative or access to the automated information system, call  
800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Amadeus S Lopez

Examiner

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November 21, 2006



TEENA MITCHELL  
PRIMA MINER

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